K061558

JUN 29 2006

Exhibit #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland

Max Schmidheiny-Strasse 201
9435 Heerbrugg / Switzerland

Date Summary Prepared: June 2, 2006

Contact: Mr. Gerhard Frick

2. Name of the Device:

Microlife Wrist Watch Blood Pressure Monitor, Model BP3BU1-4U

3. Information for the 510(k) Cleared Device (Predicate Device):

Microlife Wrist Watch Blood Pressure Monitor, Model BP3BU1-5, K#040002.

4. Device Description:

The Microlife Wrist Watch Blood Pressure Monitor, Model BP3BU1-4U is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a technique in which an inflatable cuff is wrapped around the wrist. Our method to define systolic and diastolic pressures is similar to the auscultatory method but uses an electronic semiconductor pressure sensor rather than stethoscope and mercury manometer. The sensor converts tiny alteration in cuff pressure to electrical signals; by analyzing those signals to define the systolic, diastolic and calculating pulse rate is a well known technique in the market called the "oscillometric method". The device can be used in connection with your personal computer **(PC)** running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

5. Intended Use:

Microlife Wrist Watch Blood Pressure Monitor, Model BP3BU1-4U is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a technique in which an inflatable cuff is wrapped around the wrist.

The device can be used in connection with your personal computer **(PC)** running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

Both devices use the well-known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. Wrist cuff is inflated automatically; deflate rate is controlled but a factory set bleed valve and the deflation pressures are transferred via tubing to a sensor in both units. They use semiconductor pressure sensor instead of capacitive pressure sensor to translate the pressure variations to electrical signals that can be interpreted by an integrating circuit. Moreover both devices have a MAM function.

The difference between BP3BU1-4U and the predicate device is the addition of a PC function. The device can be used in connection with your personal computer **(PC)** running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the Microlife Wrist Watch Blood Pressure Monitor, Model BP3BU1-4U in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

The following testing was conducted:

a. Reliability Test - StorageTest
b. Reliability Test - Operating Test

c. Reliability Test - Vibration Test
d. Reliability Test - Drop Test
e. Reliability Test - Life Test
f. EMC Test
g. PC-link software BPA Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the Microlife Wrist Watch Automatic Blood Pressure Monitor, Model BP3BU1-4U tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

ANSI/AAMI SP10-2002 "National Standard for Manual, Electronic or Automated Sphygmomanometers" testing was performed on our predicate device. All relevant sections were addressed and testing conducted. The BP3BU1-4U met all relevant requirements of this standard, as applicable to our modified device. Repeat testing was not performed for the modified device, as clinical testing results were not affected by the changes to the modified device.

9. Software information:

In keeping with current FDA policy on software level of concern, the modified device is consistent with a moderate level of concern. We provided software documentation in accordance with the FDA November 2005 document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices ". Moreover, the subject device requires the use of off-the-shelf software to operate the PC-link function, and we met all required elements as outlined in FDA's "Off the Shelf Software Guidance Document".

10. Conclusions:

We have demonstrated that the Microlife Wrist Watch Blood Pressure Monitor, Model BP3BU1-4U, is as safe and effective as our predicate, the Microlife Wrist Watch Blood Pressure Monitor, Model BP3BU1-5 based on electrical, mechanical and environmental testing results as well as the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and our "Risk Analysis", as supplied with this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2006

Microlife Intellectual Property GmbH
c/o Susan D. Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd, Suite 200
Great Neck, NY 11021

Re: K061558
Trade Name: Microlife Wrist Watch Blood Pressure Monitor Model BP3BU1-4U
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: June 2, 2006
Received: June 5, 2005

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Brain D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit# B

Indications for Use

510(k) Number (if known): K061558

Device Name: Microlife Wrist Watch Blood Pressure Monitor, Model BP3BU1-4U

Indications For Use:

The Microlife Wrist Watch Blood Pressure Monitor, Model BP3BU1-4U is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a technique in which an inflatable cuff is wrapped around the wrist.

The device can be used in connection with your personal computer **(PC)** running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

Prescription Use _____ **AND/OR** **Over-The-Counter Use** X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061558